Applicant: HICKOK, et al. Attorney's Docket No.: 18.006011

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Listing of the Claims:

1-66 (canceled)

67. (currently amended): A method of screening and treating a subject, comprising: a) obtaining a sample from a subject who is asymptomatic for preterm or imminent delivery; b) detecting the level of a fetal restricted antigen in said sample from said subject and assessing whether the level of fetal restricted antigen is indicative of a risk of preterm or imminent delivery; and c) if the level of fetal restricted antigen is indicative of the risk, administering a progestational agent to the subject, whereby delivery is delayed.

68. (currently amended): The method of claim 67, wherein, wherein the sample contains a body fluid or cells collected from a swab of the posterior fornix, or the cervical canal, or the ectocervix and/or the external cervical os.

69. (previously presented): The method of claim 67, wherein a level indicative of the risk is above a minimum threshold amount.

70. (previously presented): The method of claim 67, wherein a level indicative of the risk is below a maximum threshold amount.

71. (currently amended): The method of claim 67, wherein the progestational agent is administered after the start of fetal organogenesis.

72. (previously presented): The method of claim 67 wherein the sample is obtained after about 12 weeks gestation.

73. (previously presented): The method of claim 67, wherein the sample is obtained after about 16 weeks gestation.

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74. (previously presented): The method of claim 67 wherein the sample is obtained after about 20 weeks gestation.

- 75. (currently amended): The method of claim 67, wherein the administration of the progestational agent is stopped at about 36 weeks of gestation or at the onset of spontaneous labor.
- 76. (previously presented): The method of claim 67, wherein the fetal restricted antigen is fetal fibronectin.
- 77. (previously presented): The method of claim 67, wherein the progestational agent comprises at least one omega-3 fatty acid or a derivative thereof.
- 78. (previously presented): The method of claim 77, wherein the progestational agent comprises docosahexaenoic acid.
- 79. (previously presented): The method of claim 67, wherein the progestational agent is a progesterone-related agent.
- 80. (currently amended): The method of claim 79, wherein the progesterone-related agent is 17-[[.]]alpha[[.]]-hydroxyprogesterone or 17-[[.]]alpha[[.]]-hydroxyprogesterone caproate.
- 81. (currently amended): The method of claim 67, wherein the therapeutically effective amount of the progestational agent administered comprises at least about 100 mg/week of the progestational agent.
- 82. (previously presented): The method of claim 67, wherein the progestational agent is administrated

orally, by intramuscular injection, transdermally, or intranasally.

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83. (currently amended): The method of claim 67, further comprising the step of: if the level of fetal restricted antigen is not indicative of a risk of preterm or imminent delivery, repeating at intervals at least one day apart the steps of obtaining a sample from a subject who is asymptomatic for preterm or imminent delivery and detecting the level of fetal restricted antigen in the sample and assessing whether the level of fetal restricted antigen is indicative of the risk; wherein if the level of fetal restricted antigen is indicative of the risk; wherein if the level of fetal restricted antigen is indicative of the risk, administering a progestational agent to the subject, whereby delivery is delayed.

84. (previously presented): The method of claim 76, wherein the level indicative of the risk is a minimum threshold value of about 50 ng/mL.

85. (currently amended): The method of claim 76, wherein the sample is obtained from the a posterior fornix.

86. (currently amended): The method of claim 76, wherein the sample is obtained from the a cervical os.

87. (currently amended): The method of claim 76, wherein the level of fetal fibronectin is determined by the steps of: a) contacting the sample with an anti-(fetal fibronectin) antibody for a time sufficient to permit antigen-antibody binding to occur; b) <u>further</u> contacting the sample with an insoluble support, to which anti-fibronectin antibody is adhered, for a time sufficient to permit antigen-antibody binding to occur; and c) detecting anti-(fetal fibronectin) antibody on the insoluble support.

88. (previously presented): The method of claim 87, wherein material from the sample is contacted with the insoluble support in a region of the insoluble support that contains mobilizable anti-(fetal fibronectin) antibody.

89. (previously presented): The method of claim 87, wherein the anti-(fetal fibronectin) antibody is conjugated to a physically detectable label.

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90. (previously presented): The method of claim 87, wherein the step of detecting anti-(fetal fibronectin) antibody comprises the steps of: a) contacting the insoluble support with a labeled antibody which binds selectively with the anti-(fetal fibronectin) antibody; and b) detecting the label on the insoluble support.

- 91. (currently amended): The method of claim 76, wherein the level of fetal fibronectin is determined by the steps of: a) contacting the sample with an anti-fetal fibronectin antibody for a time sufficient to permit antigen-antibody binding to occur; and b) detecting formation of an antibody-antigen complex.
- 92. (currently amended): The method of claim 91, wherein the step of detecting formation of an antibody-antigen complex further comprises the steps of: c) <u>further</u> contacting the sample with an insoluble support comprising an immobilized an anti-(fetal fibronectin) antibody under conditions, whereby fetal fibronectin in the sample binds to the antibody; and d) detecting the anti-fibronectin antibody on the insoluble support.
- 93. (previously presented): The method of claim 91, wherein the anti-fibronectin antibody comprises a detectable label.
- 94. (previously presented): The method of claim 93, wherein the step of detecting the anti-fibronectin antibody comprises the steps of: e) contacting the insoluble support with a labeled antibody that binds selectively with the anti-fibronectin antibody; and f) detecting the label on the insoluble support.